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EXAMINER	
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ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/735,344	SAYADA, CHALOM B.	
	Examiner	Art Unit	
	Umamaheswari Ramachandran	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 12-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 12-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner notes the receipt of the remarks received in the office on 5/8/2007 electing lipid lowering agent as the second therapeutic agent. The species election has been made without traverse. The species read on the claims 1-8, 12-21. The claims 9-11 will be withdrawn from consideration. Claims 1-21 are pending and claims 1-8, 12-21 are examined on the merits herein.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20, 21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No.10/651,865 ('865). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and the co-pending application '865 teach a method of treating bacterial infection in a method comprising administering rifamycin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20, 21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No.10/443,351 ('351). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and the co-pending application '351 teach a method of treating bacterial infection in a method comprising administering rifamycin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 12-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for preventing atherosclerosis in a patient comprising administering rifamycin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547

the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the ad; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The Nature of the Invention:

The rejected claims are drawn to a method of treating, preventing, or reducing the development of an atherosclerosis-associated disease in a patient in need thereof, said method comprising administering to said patient a rifamycin in an amount effective to treat, prevent, or reduce the development of said atherosclerosis-associated disease in said patient.

(2) Breadth of the Claims:

The instant claims are broad and embrace preventing atherosclerosis-associated disease in a patient in need thereof, said method comprising administering to said patient a rifamycin in an amount effective to prevent the development of said atherosclerosis-associated disease in said patient.

(3) Guidance of the Specification:

The guidance of the specification is towards the prevention of atherosclerosis-associated disease in a patient in need thereof, said method comprising administering to said patient a rifamycin in an amount effective to prevent the development of said atherosclerosis-associated disease in said patient is completely lacking.

(4) Working Examples:

Applicant does not provide any working examples for the prevention of atherosclerosis-associated disease in a patient in need thereof.

(5) State/predictability of the Art:

The state of the art regarding treating atherosclerosis-associated disease in a patient in need thereof is relatively high. However, the state of the art for prevention of atherosclerosis-associated disease in a patient in need thereof is underdeveloped.

(6) The Quantity of Experimentation Necessary:

The instant claims read on the prevention of atherosclerosis-associated disease in a patient in need thereof comprising administering rifamycin. As discussed above, the specification fails to provide sufficient support for completely protecting a mammal atherosclerosis-associated disease in a patient. Applicant fails to provide information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Accordingly the claims are evaluated as a method for treating atherosclerosis-associated disease in a patient and not as a method for preventing atherosclerosis-associated disease in a patient.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 12-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Michaelis et al. (U.S 2004/0014749).

Michaelis et al. teach a method of treating a disease such as atherosclerosis comprising administering rifamycin compounds (see Abstract, p 3, para 0024). The reference further teach rifamycin compounds in a method of reducing the level of C-reactive protein in patients diagnosed with C.pneumoniae or has not been diagnosed as having a bacterial infection (p 3, para 0025). The reference also teaches a method of reducing C.pneumoniae replication, treating a persistent C.pneumoniae infection in macrophages or foam cells in a patient comprising administering rifamycin (para 0026, 27) . The reference teaches a dosage of rifamycin of about 0.001 to 100 mg/day. The reference further teaches that the compound can be administered daily or less frequently (a single dose/week, 5 to 25 mg/week) or the treatment done for one day to a year p 3, (para 0029). The reference also teaches an initial dose of rifamycin 2.5 to 100 mg for one to seven consecutive days, followed by a maintenance dose of 0.005 to 10 mg once every one to seven days for one month, one year, or even for the life of the

patient (p3, para 0029). The reference teaches that rifamycin compound may be administered in conjunction with one or more additional agents such as lipid lowering agents (e.g., cholestyramine, colestipol, nicotinic acid, gemfibrozil, probucol, ezetimibe, or statins such as atorvastatin, rosuvastatin, lovastatin simvastatin, pravastatin, cerivastatin, and fluvastatin) (p3, para 0030).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1-8, 12-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Michaelis et al. (U.S 2004/0014750).

Michaelis et al. teach a method of treating a disease such as atherosclerosis comprising administering rifamycin compounds (see Abstract, p 3, para 0038). The reference further teach rifamycin compounds in a method of reducing the level of C-reactive protein in patients diagnosed with C.pneumoniae or has not been diagnosed as having a bacterial infection (p 3, para 0039). The reference also teaches a method of reducing C.pneumoniae replication, treating a persistent C.pneumoniae infection in macrophages or foam cells in a patient comprising administering rifamycin (p3, para 0040, 41) . The reference teaches a dosage of rifamycin of about 0.001 to 100 mg/day.

The reference further teaches that the compound can be administered daily or less frequently (a single dose/week, 5 to 25 mg/week) or the treatment done for one day to a year p 3, (para 0042). The reference also teaches an initial dose of rifamycin 2.5 to 100 mg for one to seven consecutive days, followed by a maintenance dose of 0.005 to 10 mg once every one to seven days for one month, one year, or even for the life of the patient (p3, para 0042). The reference teaches that rifamycin compound may be administered in conjunction with one or more additional agents such as lipid lowering agents (e.g., cholestyramine, colestipol, nicotinic acid, gemfibrozil, probucol, ezetimibe, or statins such as atorvastatin, rosuvastatin, lovastatin simvastatin, pravastatin, cerivastatin, and fluvastatin) (p3, para 0043).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim 20 is rejected under 35 U.S.C. 102(e) as being anticipated by Mitchell et al. (U.S. 6,562,582).

Mitchell et al. teach agents against Chlamydia replication and teach the drug class rifamycin (example, rifampin) as one of the effective agents (col. 9, Table 1, line 25). The reference further tech that all members of the Chlamydia species, including C.

pneumoniae, are considered to be inhibited, and some killed, by the use of a single agent (col. 9, lines 28-30).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Kump et al. (U.S. 5,147,870).

Kump et al. teach rifamycin compounds with LDL lowering activity (hypolipidaemic agents) for the treatment of hyperlipidaemia and arteriosclerosis. This anticipates a method of treatment of atherosclerosis in comprising administering rifamycin or its derivatives (see Abstract, col. 3, lines 4-8).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Traxler et al. (U.S. 4,916,126).

Traxler et al. teach rifamycin compounds that exhibit hypolipidaemic properties and the reference further teach that the compounds are useful in the treatment of arteriosclerosis (see Abstract, col.3, lines 35-37). This anticipates a method of treatment of atherosclerosis in comprising administering rifamycin or its derivatives (see Abstract, col. 3, lines 4-8).

Claims 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Cox et al. (Annals of the Rheumatic Diseases, 1992, 51, 32-34).

Cox et al. teach that C-reactive protein concentration decreased in serum after treating the patients for six months with antibiotics rifampicin (600 mg) (see Abstract). The reference does not explicitly teach that the c-reactive protein levels are periodically monitored but the study of monitoring the c-reactive protein after 6 months anticipates the monitoring the level of c-reactive protein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 12-16, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baumgart et al (WO 00/01378) in view of Ullah et al. (U.S. 6,235,311).

Baumgart et al teach methods and pharmaceutical compositions for the treatment or prevention of conditions and vascular diseases associated with infection of Chlamydia species or similar susceptible microorganisms in a patient comprising administering an effective amount of at least two different antibiotics that includes

rifamycin (see Abstract). The reference teach C.pneumoniae has been identified in atherosclerotic plaque and incriminated in vascular disease that it is an obligate intracellular pathogen that grows within macrophages and epithelial cells (p1, lines 5-19). The reference further teaches that Chlamydia infection is associated with disorders such as atherosclerotic vascular disease affecting coronary arteries, myocardial infarction, aortic vascular disease, renovascular and glomerular disease etc (p 5, lines 7-12). The reference teaches an amount of 300 mg/day or 150 mg rifampicin administration (p8, lines 2-3, line 15), and further teaches that the established and safe dosages of antibiotics range from 0.0005 – 50 g/day depending on the agent (p 9, lines 9-10). The reference also teaches that antibiotics may be in a single daily dose or two or more doses a day or can be administered between 1 and 28 days or can be continued up to 6 months (p 9, lines 22-25).

The reference does not teach in the composition a second therapeutic agent, a lipid-lowering agent such as statin in a method of treatment of atheroscleorsis.

Ullah et al.teach a pharmaceutical composition comprising a statin such as lovastatin, simvastatin, cerivastatin, a cholesterol lowering agent for use in lowering cholesterol and reducing risk of a myocardial infarction, and to a method for lowering cholesterol and reducing risk of a myocardial infarction or treating atherosclerosis employing such composition (see Abstract, col. 1, line 60, col.5, lines 37-39).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have added a second therapeutic agent such as a lipid lowering agent in a method of treatment of atherosclerosis because Ullah et al. teach that statins are useful

in lowering cholesterol and reducing risk of a myocardial infarction or treating atherosclerosis. One of ordinary skill in the art would have been motivated to add a second therapeutic agent such as a lipid lowering agent in a method of treatment of atherosclerosis along with rifamycin because both drugs have been shown to be useful in the treatment of atherosclerosis and one can expect success and synergy and/or additive therapeutic benefits in combining both the therapeutic agents that have the same utility.

The references do not teach the dosage treatment of rifamycin as claimed in the instant application.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have a dosage treatment of rifamycin as claimed in claims 2-6 of the instant application. Baumgart et al teaches an amount of 300 mg/day rifampicin administration and further teaches that the established and safe dosages of antibiotics range from 0.0005 – 50 g/day depending on the agent and the reference also teaches that antibiotics may be in a single daily dose or two or more doses a day or can be administered between 1 and 28 days or can be continued up to 6 months. One of ordinary skill in the art would have been motivated to administer rifamycin or its derivatives in the treatment of atherosclerosis because of expectation of success and to achieve therapeutic benefits in the treatment of C.pneumoniae infection disorders as taught by Baumgart et al. It would have been obvious to one of ordinary skill in the art at the time of the invention to have a dosage treatment of rifamycin as claimed because it is clearly a result effective parameter that a person of ordinary skill in the art would

routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount and dosage therapy treatment would have been obvious at the time of applicant's invention.

Baumgart et al. do not explicitly teach that the patient associated with atherosclerosis has not been diagnosed having a bacterial infection.

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer rifamycin in a method of treatment of atherosclerosis to a patient not been diagnosed having a bacterial infection. Baumgart et al. teach a method of prevention administering rifamycin in patients and therefore it is obvious that the patient has not been diagnosed with bacterial infections and hence an antibiotic such as rifamycin is administered to patients in a preventative method.

Claims 1-5, 7, 8, 12-15, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamashita et al. (EP 0778022) in view of Baumgart et al (WO 00/01378) and further in view of Ullah et al. (U.S. 6,235,311).

Yamashita et al. teach a method of treatment of diseases such as coronary disease caused by Chlamydia infection comprising administering rifamicin derivatives (see Abstract, p 3, lines 1-5, p 9, claim 1). The reference teach an effective dose of 10 mg-10 g per day for adults (p 10, claim 9).

The reference does not teach a method of treating atherosclerosis comprising administering rifamicin.

Baumgart et al's teachings discussed as above. The reference teaches that Chlamydia infection is associated with disorders such as atherosclerotic vascular disease affecting coronary arteries, myocardial infarction, aortic vascular disease etc.

It would have been obvious to one of ordinary skill in the art at the time of administration to use rifamicin or its derivatives in a method of treatment of atherosclerosis because Baumgart et al. clearly teaches atherosclerosis as one of the disorders associated with Chlamydia infection and Yamashita et al. teach the use of rifamycin derivatives in treatment of diseases such as coronary disease caused by Chlamydia infection. A person of ordinary skill in the art would have been motivated to administer rifamycin in the treatment of atherosclerosis in the expectation of success and to achieve desired therapeutic benefits of the drug as taught by Baumgart.

The references do not teach in the composition a second therapeutic agent, a lipid-lowering agent such as statin in a method of treatment of atheroscleorsis.

Ullah et al.teach a pharmaceutical composition comprising a statin such as lovastatin, simvastatin, cerivastatin, a cholesterol lowering agent for use in lowering cholesterol and reducing risk of a myocardial infarction, and to a method for lowering cholesterol and reducing risk of a myocardial infarction or treating atherosclerosis employing such composition (see Abstract, col. 1, line 60, col.5, lines 37-39).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have added a second therapeutic agent such as a lipid lowering agent in a

method of treatment of atherosclerosis because Ullah et al. teach that statins are useful in lowering cholesterol and reducing risk of a myocardial infarction or treating atherosclerosis. One of ordinary skill in the art would have been motivated to add a second therapeutic agent such as a lipid lowering agent in a method of treatment of atherosclerosis along with rifamycin because both drugs have been shown to be useful in the treatment of atherosclerosis and one can expect success and synergy and/or additive therapeutic benefits in combining both the therapeutic agents that have the same utility.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER